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NUTTER, N

153

07/11/91

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 7 are pending in the application.
Of the above, claims 4 - 7 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 - 3 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☒ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Art Unit 153

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, drawn to an hydroxethyl starch, classified in Class 536, subclass 111.

II. Claims 4-7, drawn to a process for producing starch ethers, classified in Class 536, subclass 124 plus.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and of Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product such as other starch ethers and the product as claimed can be made by a materially different process such as shown by the Morishita Pharmaceutical Patent (G.B. 1 395 777).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification restriction for examination purposes as indicated is proper.

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Art Unit 153

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

During a telephone conversation with Omri M. Behr on 21 June 1991 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this election must be made by applicant in responding to this Office action. Claims 4-7 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over Nitsch et al or Staley Manufacturing (G.B. 935,339).

The reference to Nitsch et al teaches the production of an hydroxyethyl starch useful as a plasma expander which may include starch derivatives having molecular weights in the range of, preferably, 200,000 to 450,000 Daltons, which lies within the range recited by applicants in the instant claims. Note column 3 (lines 21-24). At column 3 (lines 25-28) for a molar substitution of 0.1 to 0.8.

Although the reference does not specify ratio of C2 to C6 substitution of the anhydroglucose units, such would have been manipulable to a practitioner having an ordinary skill in the art to provide maximum benefits obtained thereby. The compounds of the claims are employed in identical capacities as the reference. Thus, the production of an hydroxyethyl starch plasma expander as recited in the instant claims would have been obvious from the reference to a practitioner having an ordinary skill in the art at the time the invention was made.

The reference to Staley Manufacturing (G.B. 835,339) cited of interest, teaches the production of an hydroxy ethyl starch

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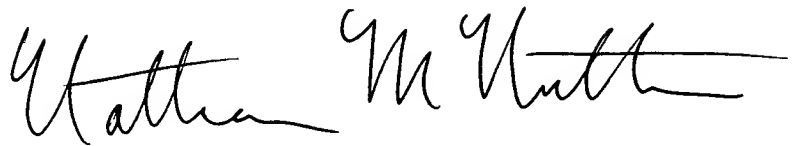
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derivative which has a molar substitution greater than 0.15 at page 1 (lines 52-60). Further, note Tables I and II at pages 6 and 7.

Nutter:ltd
July 10, 1991
(703)308-2351

8-9-91

A handwritten signature in cursive script, appearing to read "Nutter M Nutter", written in dark ink.

**NATHAN M. NUTTER
PATENT EXAMINER
ART UNIT 153**